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TuFlux TPE tubing for pharma processing

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TuFlux® TPE

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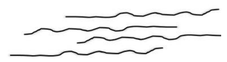
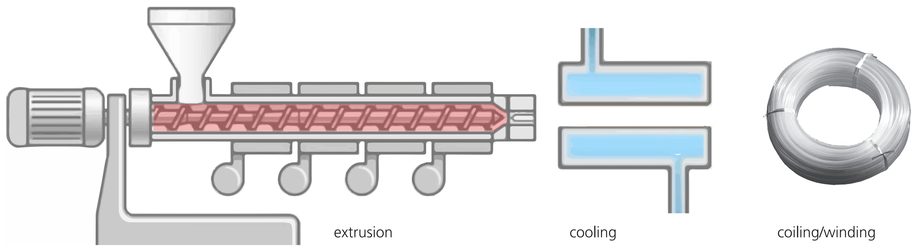
The requirements for products, being supplied to the pharmaceutical and medical industry are getting higher almost every day. Clean room production, FDA-Certification, and several other certifications according to different standards is the base of new products and developments.
No matter if the product is used in final filling applications, medical devices or as long-term implants. Only with a very high level of material expertise and application experience it is possible to supply to such highly regulated markets.

Thermoplastic Polymers



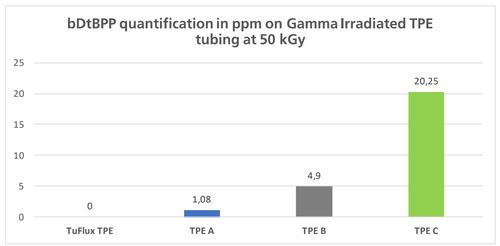
Raw material is melted in the extruder using temperature and shearing energy from the screw. Using a ring/pin-dye the hot melt is shaped and cooled in water. Finally coiled or cutt in short pieces. This gives the opportunity to fullfill individual customer requests. The choice of raw-materials is always based on the final application. Key properties of thermoplastics are linear molecular chains without cross links, shape- and re-shapeable with heat, "easy" to deform mechanically. Sealable and weldable.

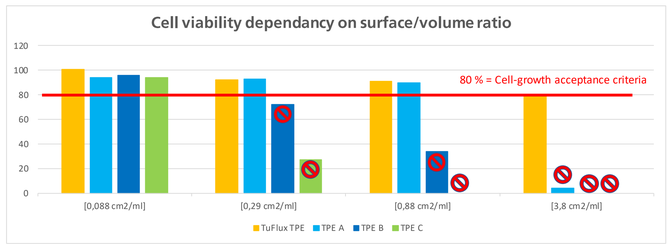
Most important processing steps: Heating/plastification, shaping, cooling, coiling/winding



Extractables Profiles

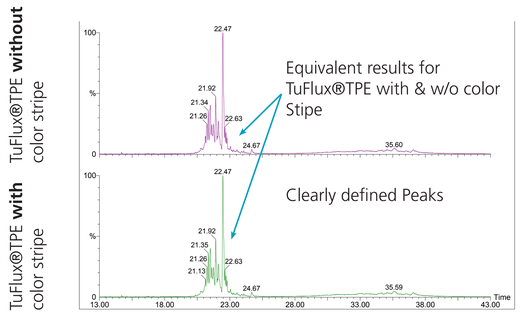
TuFlux TPE – A new benchmark in cell growth

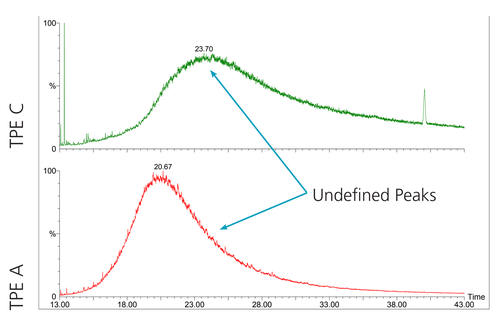




Synthetic Oil vs Paraffinic Oil

- → Clear peaks in chromatogramm for better E/L identification
- → Highest „batch to batch" reproducability with synthetic oil
- → Chromatograms show no difference between colored and non colored tubes

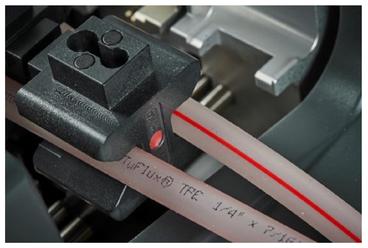




RAUMEDIC® Lifeline to Health | sartorius stedim biotech

(Co-)Welding and Sealing

- → Welding/ Sealing of TPE tubing is the crucial application advantage in comparison to silicone tubing
- → SSB's Bio-Welder and –Sealer are the best in class welding systems
- → SSB controls welding/ sealing parameters



Key-Features/USPs

- → (Co-)Weldable with all common TPE tubes in the market
- → Color-coding for error prevention in use
- → „Clear", well-defined, extractables profile
- → Long time security of supply
- → Extensive validation data
- → Sterilizable with all common methods (Gamma, ETO and Autoclaving)
- → 7 standard dimensions are available ex-stock SSB
- → Process control (DoE)

Process control

- → RM performs a DoE on the TuFlux TPE in collaboration with SSB
- → Critical process parameters for production are identified and analyzed in order to enhance process capability and product quality
- → During numerous production runs upper, lower and nominal process parameters are tested to achieve the highest possible degree of product safety
- → Ultimate goal of DoE: Establishment of a process window that ensures final products always being within specification.

Supply Chain

Raw material supplier → Converter (RAUMEDIC) → Set assembly (Sartorius Stedim Biotech) → Final user

For better product development and to serve customer needs, it is very important to integrate as much parties as possible within the whole supply chain.
A very good example is the cooperation between Sartorius Stedim Biotech and RAUMEDIC.